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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,387

01/05/2006

David Peter Shaw

PL10-002

3069

21567

7590

08/08/2007

WELLS ST. JOHN P.S.

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

08/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/563,387

Applicant(s)

SHAW, DAVID PETER

Examiner

Ann Schillinger

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3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/5/06, 4/18/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claims 2-9 are objected to because of the following informalities: they are dependent claims that begin with indefinite articles. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (EP 0 331 345 A2). Silvestrini discloses the following of claim 1: a prosthetic valve in the form of a flap valve which includes at least one flap (12) arranged to allow movement of liquid through the valve only in one direction, the or each flap being made of a flexible openwork structure of a medically acceptable metal (col. 3, lines 2-23).

Silvestrini discloses the following of claim 2: a prosthetic valve as claimed in claim 1 wherein said valve includes a single flap (12) arranged to close against a supporting wall (16) mounted upon a peripheral stent (14).

Silvestrini discloses the limitations of claims 3 and 5 as shown in Figure 1.

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Silvestrini discloses the peripheral rib of claim 6 in col. 2, lines 23-26.

Silvestrini discloses the peripheral stent of claim 7 in element 14.

Silvestrini discloses the limitations of claims 8 and 13 in col. 2, lines 27-38, and col. 3, lines 19-31.

Silvestrini discloses the following of claim 10: a method of promoting tissue growth and endothelialisation, minimising the risk of foreign body infection following the fitting of a prosthetic valve in a living subject (col. 1, line 4-6), said method including the provision of a prosthetic valve in which the or each flap (12) is made of a flexible open work structure of a medically acceptable metal (col. 3, lines 2-23).

Silvestrini discloses the limitations of claim 11 in col. 1, lines 4-6.

Claims 1-7, 10, and 11 rejected under 35 U.S.C. 102(e) as being anticipated by Palmaz et al. (US Pub. No. 2003/0023303). Palmaz et al. discloses the following of claim 1: a prosthetic valve in the form of a flap valve (10) which includes at least one flap (28) arranged to allow movement of liquid through the valve only in one direction, the or each flap being made of a flexible openwork structure of a medically acceptable metal (paragraphs 0043, 0071).

Palmaz et al. discloses the following of claim 2: a prosthetic valve as claimed in claim 1 wherein said valve includes a single flap (28) arranged to close against a supporting wall (22) mounted upon a peripheral stent (12).

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Palmaz et al. discloses the limitations of claims 3 and 5 as shown in Figure 2.

Palmaz et al. discloses the following of claim 4: a prosthetic valve as claimed in claim 3 wherein said valve also includes a peripheral stent (12) supporting a wall (22) extending at right angles to the plane of the stent and providing two opposed cutouts (24) in which said the flaps are mounted (see Figure 4).

Palmaz et al. discloses the peripheral rib of claim 6 in element 22.

Palmaz et al. discloses the peripheral stent of claim 7 in element 12.

Palmaz et al. discloses the following of claim 10: a method of promoting tissue growth and endothelialisation, minimising the risk of foreign body infection following the fitting of a prosthetic valve (10) in a living subject (paragraph 0078), said method including the provision of a prosthetic valve in which the or each flap (28) is made of a flexible open work structure of a medically acceptable metal (paragraphs 0043, 0071).

Palmaz et al. discloses the limitations of claim 11 in paragraph 0078.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini in view of Palmaz et al. Silvestrini discloses the invention substantially as claimed,

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however, Silvestrini probably does not disclose making the flaps paragraph 0071 for the purpose of utilizing the material's biocompatibility and mechanical properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the flaps out of titanium in order to utilize the material's biocompatibility and mechanical properties.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini or Palmaz et al. in view of Yang (US Pub. No. 2002/0138138). Palmaz et al. discloses the invention substantially as claimed, however, Palmaz et al. probably does not disclose placing an inert degradable coat over the valve. Yang teaches this coating in paragraph 0059 for the purpose of reducing the wear of the prosthetic parts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this coating in order to reduce the wear of the prosthetic parts.

### *Conclusion*

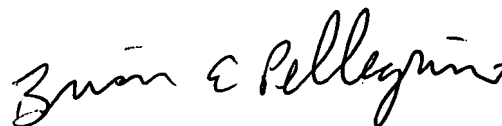
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger  
August 3, 2007



**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**